POCKET VASCULAR DOPPLER

SONOTRAX-D

MANUAL BOOK

Elitech® TECHNOVISION

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CAUTION

In the United States, Federal law restricts this device to sale, distribution, and use by or on order of a licensed physician.

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Chapter 1 Safety Guidance and Symbols

1.1 General Safety

Before using the device, please carefully examine the vascular doppler (hereinafter called device) and the accessaries to ensure the main unit and accessaries do not have any visible damage evidance that may affect patient safety and device performance. The recommended examination period is once per week.

The device is not feasible to use in the environment with electrical surgical equipments.

Installment, adjustment, maintenance and reparation can be carried out only by qualified or authorized personnels from manufacturer.

It is forbiddened to copy or translate any part of the content of the manual to other languages without getting written permission from manufacturer.

Please observe the WARNING, CAUTION and NOTE to avoid possible injury.

NOTE: Before using the device, please read this manual carefully and assure to be familiar with the controls, displays, features and operating techniques.

1.2 Warnings

⚠WARNING⚠: The device is not intended for treatment.

⚠WARNING⚠: This device is not explosion-proof and can not be used in the presence of flammable anaesthetics equipment.

⚠WARNING⚠: Do not throw battery into fire as this may explode and cause danger.

⚠WARNING⚠: Do not attempt to recharge normal dry-cell battery, which may leak and cause fire.

⚠WARNING⚠: Use adapter complying with IEC60950.

⚠ WARNING ⚠ : Do not touch signal input or output connector and the patient simultaneously to avoid device damage.

⚠WARNING⚠: Accessory and equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards.

⚠WARNING⚠: The battery must be taken out from the battery compartment if the device will not be used for a long time.

⚠ WARNING ⚠ : Replacing battery shall only be done outside the patient environment (1.5m away from the patient).

⚠WARNING⚠: Please use the specialized probes provided by the manufacturer.

⚠WARNING⚠: Do not pull the line of probe longer than 2 meters, or else the probe may break away from the connector of the device.

⚠ WARNING ⚠ : The device is designed for continuous operation and is ordinary. Do not immerse in any liquid (i.e. not drip or splash-proof).

⚠WARNING⚠: Keep the device clean. Avoid vibration.

⚠WARNING⚠ : Do not use high temperature sterilizing process and E-beam or gamma radiation sterilization.

⚠WARNING⚠: The device is not subject to any sources of strong electromagnetic interference, such as radio

transmitters, mobile telephones, etc. because of electromagnetic interference.

⚠WARNING⚠: The device can not be used when some equipments are used, such as high frequency electrical generator, microwave oven and mobile phone.

⚠WARNING⚠: Do not use the device in the presence of flammable anesthetic mixture with oxygen or other flammable agents.

⚠WARNING⚠: Please stop using the device to deal with properly if the device construction is not integrated,such as the battery cover is lost.

⚠WARNING⚠: The device is feasible for relatives such as operator, responsible organization and environmental restriction, which do not need special skills, training and knowledge.

⚠WARNING⚠: This operation manual is written at a level without special education, training and other needs of individual for whom they are intended. The operator needs to have relative qualification certificate.

⚠WARNING⚠: This minimum qualifications of service personnel is to be familiar with our device operation and service technique.

⚠WARNING⚠: The following safety check should be performed once every half a year or as specified in the institution's test and inspection protocol by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

(1) Inspect the equipment for mechanical and functional damage.

(2) Inspect the safety relevant labels for legibility.

(3) Verify that the device functions properly as described in the instructions for use.

(4) Test the patient leakage current according to IEC 60601-1.

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

1.3 Cautions

⚠CAUTION⚠: The battery must be properly disposed according to local regulation after use.

⚠CAUTION⚠: The battery must be taken out from the battery compartment if the device will not be used for a long time.

⚠CAUTION⚠: The device shall only be used when the battery cover is closed.

⚠CAUTION⚠: Please do not set anode and cathode of the battery wrongly.

⚠CAUTION⚠: The device usage life is 5 years, after which please treat according to relative regulations.

⚠CAUTION⚠: Do not allow any liquid to enter the device, and do not immerse any part of the device into any liquids.

1.4 Symbols

Symbol	Explanation
	Type BF

	Refer to the operation manual
	Headphone socket
On/Off	Power On/Off
P/N	Part number
S/N	Serial number
	Date of manufacture
	Manufacturer
	Avoid the rain
	Attention, refer to the accompanying documents
	Waste electrical and electronic equipment alone processing signs (please comply with local laws and regulations)

Chapter 2 Introduction

2.1 Intended Use

The device is used to detect arterial and venous blood flow velocity or blood flow frequency shift to assess the Peripheral vascular disease and revascularization after operation.

The device can be used in these fields.

(1) Vascular velocity inspecting.
(2) Peripheral vascular assessment.
(3) ABI test to diagnose the limbs arterial disease.
(4) Blood pressure segment study.
(5) Venous compression.
(6) Penile and digit systolic pressure test and PBI value.
(7) Revascularization after operation.

2.2 Product Features

Functions	SONOTRAX-D
Display type	Colour
Display content	Wave
Touch screen	Yes
Li-ion battery	Yes
Probe detect	Yes
Earphone	Option
PC software	Option

Carry bag	Option
5 MHz probe	Option
8 MHz probe	Yes

Remark: “Yes” means the device has the function

“No” means the device don’t have the function

“Optional” means can choose this function

2.3 Standard Configuration

No.	Name	Quantity
1.	Main Body	1 pc
2.	Probe	1 pc
3.	Battery	1 pc

Chapter 3 Appearance

3.1 Main Unit

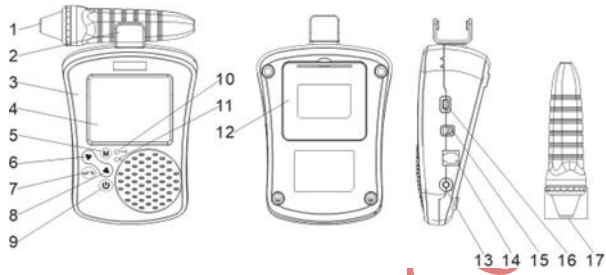

Figure 3.1 Front and Side View

Parts list is as follows;

(1) Probe

(2) Probe Clamp

(3) Main Unit

(4) Display Area

(5) Menu Key

(6) Volume Up Key

(7) Confirm Key

(8) Volume Down Key

(9) Power On/Off

(10) Charging Indicator

(11) Power Indicate Light

(12) Battery Case

(13) Earphone Port

(14) Probe Connection Port

(15) DC Port

(16) USB Port

(17) Water-proof Parts

3.2 Display

The display mode

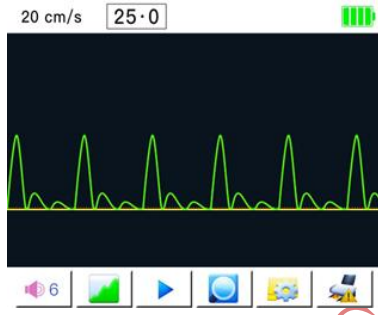

Figure 3.2 Waveform

20 cm/s: calibration value of curve -- adjust calibration scale automatically according to the measurement signal size to ensure the best signal display effect.

32·0 Is the average blood flow velocity value.

Battery capacity indicator.

Volume: 0 is mute, adjustable from 0 to 7.

Interface switch: the current interface is waveform.

Interface switch: the current interface is parameter.

Freeze: when the arrow is displayed in the upper right corner, it represents entering the freeze function. When frozen, the data is automatically saved. Operate the "up" and "down" buttons to switch the display waveform of the four screens under the save group.

Reserved function, Zoom in function.

Save icon: when the arrow is displayed in the upper right corner, it indicates that the saved state has been entered.

Print key to start printing till the setting printing time. When printing, press key to stop printing.
Other functions are reserved for function.

3.3.1 Menu Description

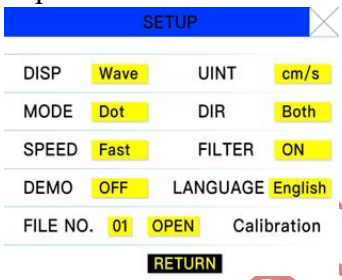

Figure 3.3 Menu Description

DISP: display interface setting, Wave interface Data digital interface.
UINT: unit cm/s,KHz switching.
MODE: set the wave display effect, Dot for contour Line and Line for filling.
DIR: unidirectional and bidirectional display switching.
SPEED: set the SPEED of wave scanning display.
FILTER: switch 80HZ or 200HZ filtering
DEMO: enter the software calibration state.
LANGUAGE: LANGUAGE setting.
FILE NO.: manually select the saved data FILE number and open the FILE.
RETURN: exit menu

3.3 Controlling Keys

In main unit configuration, there are five keys as follows.

3.3.1 Menu Key

Press this key to enter into menu setup. When finishing setting parameters, press this key to exit menu setup and enter into work state.

3.3.2 Up Key

When entering into menu setup, press this key to select sub-menu or parameters from down to up.

When the device is working, press this key to increase speaker volume.

3.3.3 Down Key

When entering into menu setup, press this key to select sub-menu or parameters from up to down.

When the device is working, press this key to reduce speaker volume.

3.3.4 Confirming Key

When finishing selecting sub-menu and parameters, press this key to confirm the selected sub-menu and parameters.

3.3.5 Turning On/Off

Press once to turn on the device.

When the device is working, press this key for 3 seconds to turn off the device.

3.3.6 Freeze Button

Freeze the current display curve; Save the current display data and the first three screens (if measured long enough).

3.4 Indicating Lights

There are two indicting lights in main unit configuration.

3.4.1 Power Indicator Light

When turning on the device, the light is bright all the time.

3.4.2 Charge Indicator Light

When charging, it is orange colour. After finishing charging, it is green.

3.5 Parameters Explanation

MENU	Parameter
DISP	Wave,Data
UINT	KHz,cm/s
MODE	Line, Dot
DIR	Both, Single
SPEED	Slow, Fast
FILTER	OFF, ON
DEMO	OFF, ON
LANGUAGE	English
FILE NO.	01-32, OPEN
RETURN	/

Chapter 4 Basic Operation

4.1 Preparing to Use

Carefully check if the device has any damnification and if the accessaries are integrated. If so, please stop using the device and contact manufacturer or local distributor. Keep the package for future transportation or storage.

4.2 Using Battery

Taking out the battery and placing battery must be guided by the manufacturer.

4.3 Operating Probes

4.3.1 Taking out and Inspecting the Probe

Hold the device main unit with one hand, hold the left part of the probe with another hand. Take out the probe along the left direction as follows.

On the contrary, you can easily fix the probe into probe clamp along the opposite direction of arrow.

When the device is power on, if the probe is not connected well with main unit, the LCD displays "— — —" and flash. After connecting well, LCD screen will stop flashing and display the probe frequency value.

4.3.2 Replacing Probe

Before replacing probe, please turn off the device.

Press the spring plate of crystal head, pull out the plug of the probe from its socket, then connect the probe you need to the socket.

4.4 Turning ON the Device

Turn on the device by pressing the power key once, the indicator light is bright.

4.5 Setting Parameter and Working Operation

1) Press M menu key to enter into menu set to set working parameters. Press ▲ up key and ▼ down key to select sub menu and parameter. Press ↵ confirmation key to confirm the selected sub menu and parameter. Finish setting the parameters, press M menu key to exit setting state and begin to work.
   The setting parameters are automatically saved.
   When working, press ▲ up key and ▼ down key to increase or reduce the volume.
2) At the bottom of screen, the work state is displayed.
3) When working, pressing the button on the probe will save the data. It can save 32 groups of data storage, each group can save 4 screen display content.

4.6 Freezing, Storing and Playing Back

When working, press ↵/✱ key to freeze the FHR or FHR curve on LCD will be freezed. This will keep till another measurement starts or the mode is changed.

Under freezing state, by pressing ▼ up or ▲ down key, the storage data can be played back with displaying FHR curve and time mark of 2 minutes length for every picture.

4.7 Turning OFF the Device

When the device is power on, press the power ON/OFF key again for 3 seconds, the device is power off and the working indicator light is off.

NOTE: The device will automatically turn off in 3 minute if it is not used.

4.8 Replacing or Charging the Battery

When the device warns the battery volume is not enough, please turn off the device and replace or charge the battery.

For charging the rechargeable battery in the machine, insert the DC plug into the device charge socket, and connect the device AC plug to the AC110-240V, 50/60Hz power supply.

It will take about 2 hours to fully charge the battery. When charging, the LED of the charger is orange; when the battery is fully charged, the LED turns to green.

⚠**CAUTION**⚠: When working, the rechargeable 7.4V Li-ion battery can not be recharged. You must turn off the Doppler before charging the battery.

⚠**CAUTION**⚠: The device can be used only when the charger is disconnected with the device.

Chapter 5 Vascular Inspecting

5.1 Gel Usage

5.1.1 Selecting Probe

According to inspecting requirement, selecting appropriate probe. The 8MHz probe has higher resolution and wider inspecting range than 5MHz probe, but 5MHz probe can inspect deeper vascular flow

5.1.2 Gel Usage

Apply ultrasound gel on the probe cover surface to reduce noise and improve test results.

5.1.3 Vascular Inspecting

Finish setting mode and parameters, press power key to start work, press power key again to stop working.

Place the working faceplate at 45° to the skin surface at inspecting location with feasible tight contact. Adjust the probe position to obtain an optimum audio signal

5.1.4 Adjusting Volume

When device is working, you can adjust volume by pressing Up or Down key to adjust volume.

5.1.5 Cleaning Work

After finishing using the device, please turn off the equipment in time and wipe the gel on the probe and skin, put the probe into the probe clamp.

5.2 Blood Pressure Testing

For Infant, child and emergency patient whose systolic pressure is usually very low, if using vascular doppler

together with normal stethoscopy, it is more easy to get the correct pressure value

5.3 Segment Systole Blood Pressure Testing

The vascular doppler together with normal stethoscopy and ankle/brachial blood pressure can be tested.

5.3.1 ABI Index Testing

ABI=ankle blood pressure/brachial blood pressure

Parameter	Numeric range	Judgement Result
ABI	>1.40	Noncompressible
ABI	1.00-1.40	Normal
ABI	0.91-0.99	Borderline
ABI	≤0.90	Abnormal CL

5.3.2 PBI Index Testing

PBI=penile blood pressure/brachial blood pressure

It is normal when PBI≥0.75

It is abnormal when PBI<0.75

5.3.3 Segmental Pressure Testing

Test segmental blood pressure difference of leg-knee upper, knee upper-knee bottom, knee bottom -ankle, if the difference is less than 30mm Hg, it is normal. If the difference is more than 30mm Hg, it is abnormal

Chapter 6 Cleaning and Disinfecting

6.1 Cleaning

Before cleaning the device, switch off. Keep the outside surface of the device clean and free of dust and dirt, clean exterior surface with a dry, soft cloth. If necessary, clean the chassis with a soft cloth soaked in a solution of soap, or water and wipe dry with a clean cloth immediately.

Wipe the probe with soft cloth to remove any remaining gel. Clean with soap and water only.

6.2 Disinfecting

Clean the equipment case, probe, etc. as above, and then wipe the probe with an alcohol impregnated wipe (70% ethanol).

Wipe the probe with a clean, dry cloth to remove any remaining moisture.

Chapter 7 Maintenance and Troubleshooting

7.1 Maintenance

The device is precision equipment, and the probe acoustic surface is frangible, you need to handle the device especially probe with enough care.

Gel and dirty dunghill must be wiped from the probe after using.

Before use, the user must check that the equipment does not have visible evidence of damage that may affect patient safety or device capability. The recommended inspection interval is once per week. If damage is evident, reparation is recommended before use.

The equipment should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement. The recommended testing interval is once every two years or as specified in the institution's test and inspection protocol.

7.2 Troubleshooting

When using, if it appears following problems, please treat by following instruction. If fail to treat, please contact local distributor or manufacturer.

7.2.1 No Sound

Main reasons: (1) The battery volume is serious insufficient; (2) The equipment is damaged; (3) The battery connection line is damaged.

Solution: (1) Charge the battery or change battery; (2) Inspect the device; (3) Contact distributor or manufacturer.

7.2.2 Weak Sound

Main reasons: (1) Voice volume is too low; (2) Battery volume is too low; (3) Without or insufficient gel.

Solutions: (1) Adjust higher voice volume; (2) Change or charge the battery; (3) Add sufficient gel on probe inspecting surface.

7.2.3 High Noise

Main reasons: (1) Probe is too near from the main unit; (2) Disturbance from the outside signal; (3) Battery volume is too low.

Solutions: (1) Keep the probe far enough from main unit; (2) Be away from outside signals; (3) Change or charge battery.

7.2.4 Low Sensitivity

Main reasons: (1) Probe position is incorrect; (2) Without or insufficient gel.

Solutions: (1) Keep the probe at right position; (2) Daub sufficient gel.

Chapter 8 Warranty and After-sale Service

8.1 Warranty

Manufacturer obligation under this warranty is limited to repair any part or whole unit upon manufacturer examination to prove they are within warranty period and range. If the product does not function during the warranty period, we will repair or replace it free of charge.

Limit of warranty:

1. Trouble resulting from misuse, negligence, accident or transportation.
2. Opening, modification or repair by unauthorized persons from manufacturer.
3. Replacing or removing serial number label or manufacturer label.

8.2 After-sale Service

If you have any questions about use, maintenance, technical specifications or malfunction of device, please contact local distributor or manufacturer.

Chapter 9 Product Specifications

9.1 Product Name

Product Name: Pocket Vascular Doppler

9.2 Model

Model: SONOTRAX-D

9.3 Safety Standard

IEC 60601-1:2005/A1:2012, IEC 60601-1-2:2014

9.4 Classification

9.4.1 Anti-electroshock Degree: Type BF equipment 

9.4.2 Liquid Proof Degree: IPX1, Ordinary equipment (sealed equipment without liquid proof)

9.4.3 Degree of Safety in Presence of Flammable Gases: Equipment not suitable for use in presence of flammable gases

9.4.4 Working System: Continuous running equipment

9.4.5 EMC: Group I Class B

9.5 Physical Characteristic

9.5.1 Size: 135 mm × 100 mm × 65 mm

9.5.2 Weight: About 650 gr (including battery)

9.6 Environment

9.6.1 Working:
Temperature: 5℃~40℃
Humidity: 25-80%
Atmospheric Pressure: 70~106KPa
9.6.2 Transport and Storage:
Temperature: -10℃~55℃
Humidity: ≤ 93%
Atmospheric Pressure: 50~106KPa

9.7 Display

Display: 65 mm ×50 mm LCD

9.8 Performance

9.8.1 Audio Output Power: 0.5W
9.8.2 Probe Frequency: 8MHz ± 10%, 5MHz ± 10%
9.8.3 Transducer Effective Radiating Area 14mm2 ± 15%
9.8.4 Vascular Frequency: 0-2KHz

9.9 Battery Type

7.4V Li-ion rechargeable battery

9.10 Recommended Coupling Medium

9.10.1 Stimulation to Skin: No
9.10.2 Total Germ Quantity: <1000units/g

9.10.3 Dung Escherichia Coli,Pseudomonas Aeruginosa and Staphylococcus aureus: No
9.10.4 Acoustic Velocity: 1520-1620m/s
9.10.5 Acoustic Impedance: 1.5-1.7x106 Pa.s/m
9.10.6 Acoustic Attenuation: <0.05dB/(cm.MHz)
9.10.7 Viscosity: >15Pa.S
9.10.8 PH Value: 5.5-8

9.11 Material Group: I
9.12 Pollution Degree: II
9.13 Operating Altitude: <2000m
9.14 Overvoltage Class: I

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